

discussed in the Legal Analysis accompanying the Utility Guidelines (M.P.E.P. § 2107). The only instances in which the Federal courts have found a lack of patentable utility were where, "based upon the factual record of the case, it was clear that the invention *could and did not work* as the inventor claimed it did." M.P.E.P. § 2107 (emphasis added). These rare cases have been ones in which the applicant either (a) failed to disclose any utility for the invention, or (b) asserted a utility that could be true only "if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art." M.P.E.P. § 2107.01.

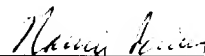
That is simply not the case here -- as is evidenced from the Jeffers paper, and the FDA's approval of Appellants' IND for the use of the claimed protein in the treatment of oral mucositis.

The rejection should be withdrawn.

#### **CONCLUSION**

In view of the foregoing comments and reasons, Appellants request that the Board of Patent Appeals and Interferences find in their favor and overturn the Examiner's Final Rejection and return their application to the Examiner with an indication that all claims before the Board in this matter fully comply with the requirements of 35 U.S.C. § 101 and 35 U.S.C. § 112 first paragraph, and are thus in condition for allowance.

Respectfully submitted,



Ivor R. Elrifi, Reg. No. 39, 529  
Naomi S. Biswas, Reg. No. 38, 384  
Attorneys for Appellants  
Mintz, Levin, Cohn, Ferris  
Glovsky and Popeo, P.C.  
Telephone (617) 542-6000  
Fax (617) 542-2241

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Please address all written correspondence to customer number 30623.